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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/257,272	02/25/1999	JING-SHAN HU	PF112P2D2	1980

22195 7590 01/05/2004

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/257,272

Applicant(s)

HU ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-48,65-96 and 113-272 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-48,65-96 and 113-272 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Formal Matters

- A. The Amendment filed 10/15/03 has been entered into the record.
- B. Claims 33-48, 65-96 and 113-272 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Double Patenting

- A. The provisional rejection of claims 33, 34, 49, 50, 65, 66, 81, 82, 97, 98, 113, 114, 129, 130, 145, 146, 161, 162, 177, 178, 193, 194, 209, 210, 225, 226, 241, 242, 257 and 258 is maintained under the judicially created doctrine of obviousness-type double patenting over the claimed invention in the following copending U.S. Applications: 09/219,442, 09/935,726, 08/465,968, and 09/107,997. Paper 32, Paragraph 3B. As stated in Applicants' previous response, on receipt of a Notice of Allowance, Applicants will either file a terminal disclaimer or cancel any conflicting claims that remain pending.

As for the claims pending in Serial No. 09/935,726 and 09/107,997, Applicants acknowledge that a clear line of demarcation will be maintained as set forth in M.P.E.P. 822.

- B. Claims 33-48, 65-96, and 113-272 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 14, 15, 18-20 of copending U.S. Application 10/060,523, claims 69-86 of copending U.S. Application 10/127,551. Claims 33, 34, 49, 50, 65, 66, 81, 82, 97, 98, 113, 114, 129, 130, 145, 146, 161, 162, 177, 178, 193, 194, 209, 210, 225, 226, 241, 242, 257 and 258 also remain provisionally rejected over one or more claims of U.S. Application 10/084,448. Applicants acknowledge these provisional rejections. Upon receipt of a notice of allowance, Applicants will file an appropriate disclaimer, to the extent that such a disclaimer is necessary, or will cancel any conflicting claims that remain pending.

- C. The rejection of claims 38-48, 70-80, 86-96, 118-128, 134-144, 150-160, 166-176, 182-192, 198-208, 214-224, 230-240, 246-256, and 262-272 under the judicially created doctrine of obviousness-type double patenting as being obvious over claims 38 and 42-71 of U.S. Application 09/499,468 has been

withdrawn in view of Applicants' cancellation of claim 38 and amendment to claim 42 to recite "a method of treating a patient having an injury to or degeneration of a photoreceptor cell" and to recite "a therapeutically effective amount" of the VEGF-2 protein. Neither of these claim amendments are disclosed or suggested by the claims recited in the above captioned application. Moreover, the process steps are not inherently taught by the above captioned application, since the treated patient must have "an injury to or degeneration of a photoreceptor cell." Therefore, the amendments to claim 42 in U.S. Application 09/499,468 obviates the provisional double patenting rejection.

3. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. All rejections under 35 USC 112, first paragraph, has been withdrawn since, as discussed during the interviews of 9/9/03 and 9/15/03, Applicants amended the claims to recite "endothelial cell proliferation" rather than "endothelial cell proliferative activity." Furthermore, the Examiner agrees with Applicants' arguments that the specification does teach the artisan how to make the "mature" and "proprotein" forms of VEGF-2.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. The rejections of claims 33-48, 65-96 and 113-272 under 35 USC 112, first paragraph, has been withdrawn since, as discussed during the interviews of 9/9/03 and 9/15/03, Applicants amended the claims to recite "endothelial cell proliferation" rather than "endothelial cell proliferative activity."

B. Claims 33-48, 65-96 and 113-160 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 8-9 of the Office Action dated 4/16/03. Applicants argue that a crucial step in determining the meaning of a technical claim term is to determine the ordinary meaning that would be ascribed by a person skilled in the relevant art. Additionally, technical publications can be used to confirm the skilled artisan's definition of a technical claim term, as well as to show that the patentee intended to apply that definition. Applicants argue that page 11, lines 11-21 of the specification defines the terms "mature" and "proprotein" and that these terms are consistent with those used in the art. They further argue that determining the amino acid sequence would be routine and that Applicants have provided a third party publication that demonstrates VEGF-2 is processed similarly in different cell types. Finally, Applicants argue that if one of skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claim is not explicitly

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Applicants argue that at the time of filing it was well known how to N-terminally sequence isolated proteins from cells transfected with a particular gene sequence. Therefore, if necessary, the skilled artisan could have routinely expressed the VEGF-2 sequence disclosed in the specification and N-terminally sequence the isolated protein, thereby identifying the amino acid sequence of the mature form.

These arguments have been considered, but are not deemed persuasive. First, though the term "mature" and "proprotein" may very well have accepted meanings to those of ordinary skill in the art, the issue remains that Applicants have not provided adequate written description of the amino acid sequence of these forms. Therefore, the skilled artisan would not know when they were in possession of the mature form or proprotein form of the VEGF receptor. These forms may, in fact, be identifiable. However, the specification does not identify these forms by a specific amino acid sequence. Similarly, even if the 'mature portion' is naturally and inherently expressed by a host cell, or is similarly expressed in various cells, the issue remains that Applicants have not provided the amino acid sequence of this protein. This written description (i.e. the exact protein sequence) may not be required for peer-reviewed journal articles. However, the bar for patentability is higher and Applicants must be in possession of what is claimed. Therefore, the Applicant has not clearly allowed the artisan to recognize that the Applicant has invented what is claimed. Applicants' definition of these terms in the specification do not remedy this situation since, again, no detail as to the structure of the mature or proprotein forms has been provided. It is believed that all pertinent arguments have been addressed.

5. Conclusion

A. No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Advisory information

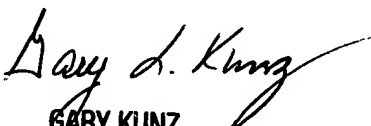
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 18, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600